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(71) Applicant *(for all designated States except US)*: BALL SEMICONDUCTOR, INC. [US/US]; 415 Century Parkway, Allen, TX 75013 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ISHIKAWA, Akira [JP/US]; 846 FM 2453, Royce City, TX 75189 (US). TAKEDA, Nabuo [JP/JP]; 2–38–7 Nishinodaira, Taihaku–ku, Sendai–si, Miyagi–ken 982–0825 (JP). AHN, Suzanne, I. [US/US]; 7918 Glen Albens Circle, Dallas, TX 75225 (US). AHN, Samuel, S. [US/US]; 256 South Beverly Glen, Los Angeles, CA 90024 (US). HAYS, Steven, R. [US/US]; 7918 Glen Albens Circle, Dallas, TX 75225 (US). GAFFNEY, F., Andrew [US/US]; 6613 Chatsworth Place, Nashville, TN 37205–3955 (US).

(74) Agent: HOWISON, Gregory, M.; Thompson & Howison, L.L.P., P.O. Box 741715, Dallas, TX 75374–1715 (US).

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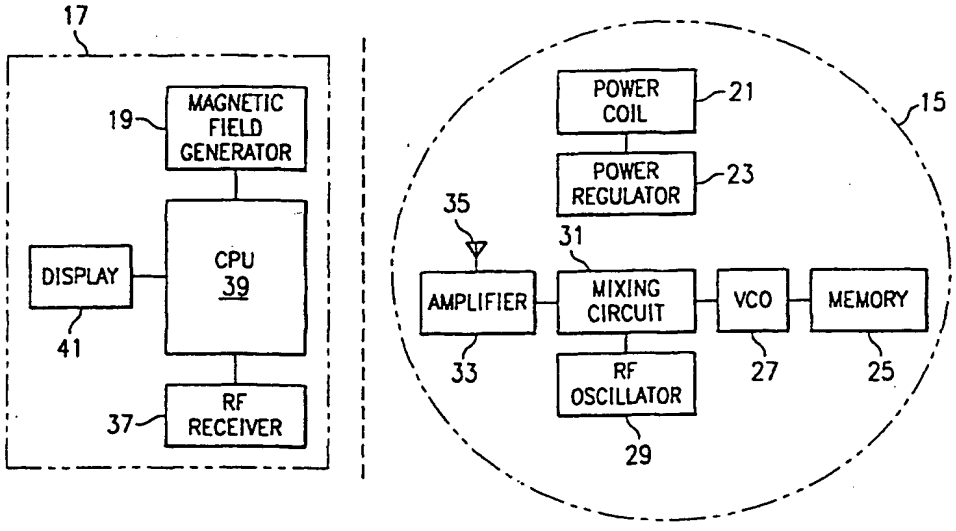

(57) Abstract

An electronic tag for identifying a medical product. A miniature passive transponder (15) comprises a power coil (21) for coupling power into the passive transponder, a power regulator (23) for regulating power to all on–board circuits, a memory (25) that contains identifying data for the medical product, a VCO (27) converting the stored data into a signal compatible for mixing, by a mixing circuit (31), with a signal of an RF oscillator (29), and an amplifier (33) for amplifying the mixed signal prior to transmission via an antenna (35) to an external monitoring system (17). Power generated from a field generator (19) of the monitoring system (17) is coupled into the transponder (15) power coil (21) to enable receipt of the memory data at an RF receiver (37) of the monitoring system (17). The RF receiver (37) connects to a CPU (39) to facilitate demodulation of the received RF signal to obtain the memory data of the transponder (15). The data may then be displayed to an operator on a display (41).

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METHOD OF AND SYSTEM FOR IDENTIFYING MEDICAL PRODUCTS

TECHNICAL FIELD OF THE INVENTION

This invention is related generally to the field of medical product inventory and control, and more particularly to a method of and system for identifying, inventorying, and locating medical products, such as pills, surgical sponges and instruments, and the like.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119(e) from U.S. Provisional Patent Application Serial No. 60/110,035 filed on November 25, 1998, having the same title as this application.

This application is related to co-pending U.S. Patent Application Serial No. 09/323,585 (Atty. Dkt. No. BASI-24,635) entitled "IMPLANTABLE EPICARDIAL ELECTRODE," filed on June 2, 1999; U.S. Provisional Patent Application Serial No. 60/137,071 (Atty. Dkt. No. BASI-24,658) entitled "GLUCOSE SENSOR," filed on June 2, 1999; U.S. Patent Application Serial No. _____ (Atty Dkt. No. BASI-24,784) entitled "SPHERICALLY-SHAPED BIOMEDICAL IC," filed of even date herewith; U.S. Patent Application Serial No. _____ (Atty. Dkt. No. BASI-24,785) entitled "MINIATURE SPHERICAL-SHAPED SEMICONDUCTOR WITH TRANSDUCER," filed of even date herewith; U.S. Patent Application Serial No. _____ (Atty Dkt. No. BASI-24,787) entitled "INTERNAL THERMOMETER," filed of even date herewith; U.S. Patent Application Serial No. _____ (Atty Dkt. No. BASI-24,789) entitled "MONITOR FOR INTERVENTIONAL PROCEDURES," filed of even date herewith.

BACKGROUND OF THE INVENTION

The existing common inventory system for medical practices does not allow for the identifying tags to be biocompatible for use in the body. There is a need to accurately identify, locate, and control medical products comprising medication, surgical sponges and instruments. The need stems from patient safety and health care provider liability concerns, as well as from cost concerns.

There are numerous problems with the current systems used to identify medications. Almost all methods of medication identification rely on various combinations of distinctive shapes, sizes, colors, and in some cases an alphanumerical coding system for the type and strength of medication. First, many drugs lack sufficiently distinctive markings. Printed markings are often difficult to read. There is no simple method for identifying the manufacturer of a given pill, yet most of the handbooks and catalogues require identification of the manufacturer before identification of the pill can occur. Information regarding lot number, date of manufacture, and expiration date is lost when the medication is repackaged by a pharmacy and dispensed as a prescription for the patient.

The lack of a simple system for positive identification of medications on a single-dose basis leads to a very complex and costly system for dispensing medications. Automated pharmacy systems exist, but verification of which medication is dispensed remains largely a manual process. Pharmacies and nurses continue to have error rates that lead to minor and sometimes major complications for patients. The lack of positive identification for medications also leads to "copycat" medicines that look like those of a large pharmaceutical firm, but which may be inferior in quality with respect to both content and bioavailability.

Even greater problems are encountered when the patients receive their prescriptions and assume control of their medicines. Often, patients are unaware of which medications they are taking. This problem is compounded when the patient receives a large number of medications, as is often the case, especially with elderly patients. To facilitate dosing, patients place their pills in smaller containers that provide the day's medications in divided doses. Millions of dollars are spent annually having trained nurses help patients with this type of dosing. Once pills are removed from their original prescription containers, it becomes very difficult to re-sort the pills

without introducing errors. Furthermore, patients may not know what medicines they may have taken or in what quantity. Large amounts of nurse and physician time are expended trying to determine which medicine the patient is taking. The situation can be impossible when there are multiple manufacturers and multiple doses of the same medication.

Patients are often brought to treatment facilities without medication records in conditions that prevent their providing an accurate medication history. Medication side effects or overdoses are often important contributors of the patients' conditions. Even when the family or nursing home staff brings the usual "bag" or list of medicines, it is not easy to determine what the patient actually took and when. Some medications may require specific "antidotes" while others require avoidance of conflicting medications. The inability of the physician to know for certain what medication(s) the patient may have taken leads to increased risks for the patient as well as increased healthcare costs for society.

Finally, with regard to medications, there is no simple way to determine whether the medication has entered the gastrointestinal track appropriately and whether it has dissolved. Problems with swallowing may cause patients' medications to stick in the esophagus. Certain types of foods and medications have a major impact on dissolution of medications once the patient takes them. There is no simple, reliable method of determining whether pills taken by the patient have dissolved or not.

In addition to problems surrounding the identification of medications, sponges and instruments are on occasions inadvertently left inside the body. X-rays are often taken looking for these instruments and sponges, leading to increased operating room and anesthetic time and increased radiation to the patient and health care personnel. This can lead to pain, suffering, and repeat surgery on part of the patient, and possible legal consequences for the doctor and the hospital. All medical items in the operating room are counted before opening the body and just before closing the body. On occasion, the count is wrong mostly because of miscounting or the instruments or other medical items having been inadvertently misplaced or discarded rather than having been left in the body. The current method of counting and finding items missing in the count prior to the closing of the patient's incision is time consuming, which means longer anesthetic time for the patient.

After surgery is completed in the operating room or after procedures anywhere in the hospital or doctor's office, valuable instruments and nondisposable items are sometimes inadvertently discarded. One does not currently know the content of the trash bag without sorting through the bag, which can be not only time consuming but unsanitary and dangerous.

SUMMARY OF THE INVENTION

The present invention disclosed and claimed herein, in one aspect thereof, comprises a method of tagging a medical product with an attached or imbedded externally powered transponder. The medical product may be a pill, a sponge, a surgical instrument, or any other medical item. The transponder includes a non-volatile memory that contains identifying data for the medical item. The item is identified by reading the memory externally of the item to obtain the identifying data. The memory is read by generating electromagnetic radiation externally of the item to power the transponder. A radio frequency (RF) signal is modulate with the identifying data, and the modulated RF signal of the item is received externally.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and the advantages thereof, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

FIGURE 1 illustrates a general block diagram of a tag/monitoring system according to a disclosed embodiment;

FIGURE 2 illustrates a more detailed block diagram of disclosed system;

FIGURE 3 illustrates a sectional view of a transponder, preferably comprising a spherical-shaped semiconductor device on which an integrated circuit has been formed;

FIGURE 4 illustrates an alternative embodiment having a pair of interconnected spherical ball devices forming the transponder;

FIGURE 5 illustrates a cross section view of the interface contacts along the line 5-5 of FIGURE 4 of a circuit ball;

FIGURE 6 illustrates a detailed block diagram of an alternative embodiment of the transponder/monitoring system, according to the disclosed architecture;

FIGURE 7 illustrates a schematic block diagram of the monitor and the transponder/monitoring system, according to a disclosed embodiment;

FIGUREs 8A-8C illustrate alternate embodiments for the transmit/receive operation;

FIGURE 9 illustrates a side view of an alternative embodiment utilizing additional circuitry or structure attached to a transponder for providing a local power source;

FIGURE 10 illustrates a schematic block diagram of a transponder having a battery as the local power supply system;

FIGURE 11 illustrates a perspective view of a transponder, wherein the inductive element is depicted as strips of conductive material wrapped around the outer region of the transponder; and

FIGURE 12 illustrates a cross-sectional diagram of the semiconductor surface of a transponder having the conductive strips which an inductive element.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIGURE 1, there is illustrated general block diagram of a tag/monitoring system according to a disclosed embodiment. A system 11 includes a pill 13 having a substantially microscopic externally-powered transponder 15 embedded therein. The pill 13 is any of several well-known types of oral medication in pill form. As will be described in detail hereinafter, transponder 15 includes a memory containing identifying data for the pill. The identifying data may comprise any combination of the following information; the identification of the medication, the dosage of the medication contained in the pill, the identity of the manufacturer of the pill, the date of manufacture of the pill, a unique serial number for the pill, and personal information of the customer to whom the pill was sold, such as name and address.

According to the disclosed architecture, the data in the memory of transponder 15 is read by an external monitoring unit, indicated generally at 17. Monitoring unit 17 may be a handheld device or it may be a fixed device in a hospital, doctor's office, pharmacy, or other facility. As will be explained in detail hereinafter, monitoring unit 17 provides power to and interrogates transponder 15, and displays or records the data read from transponder 15. Monitoring unit 17 can be used to obtain identifying information for pill 15 outside of a body or inside the body after pill 13 has been ingested. Additionally, monitoring unit 17 can obtain identifying information from transponder 15 after pill 13 has dissolved in the body, which is particularly useful in overdose situations.

The ball can also be fabricated to incorporate one or more sensors that individually or in combination detect, for example, moisture or change in pH to determine whether the pill has dissolved and exposed the ball to the environment of the gut.

Referring now to FIGURE 2, there is illustrated a more detailed block diagram of the disclosed system. The transponder 15 is a passive transponder preferably of the type disclosed (only from a functional standpoint) generally in several patents: Carroll et al., U.S. Patent No. 5,347,263, entitled "Electronic Identifier Apparatus and Method Utilizing a Single Chip Microcontroller and an Antenna Coil," issued September 13, 1994; Urbas et al., U.S. Patent No. 5,252,962, entitled "System Monitoring Programmable Implantable Transponder," issued October 12, 1993; Carroll, U.S. Patent No. 4,857,893, entitled "Single Chip Transponder

Device," issued August 15, 1989; and Hoover, U.S. Patent No. 4,345,253, entitled "Passive Sensing and Encoding Transponder," issued August 17, 1982, the disclosures of which are incorporated herein by reference. Passive transponders do not include an on-board power source such as a battery. Rather, passive transponders receive power from an external source. Monitoring unit 17 includes a power generator19. The power generator 19 directs low frequency electromagnetic radiation at transponder 15. The low frequency electromagnetic radiation generated by the power generator 19 induces a current in a power coil 21 carried by transponder 15. A power regulator 23 rectifies and regulates the current induced in power coil 21 to provide a relatively constant DC voltage level of about three volts to the circuitry of transponder 15.

Transponder 15 includes a memory indicated generally at 25. Memory 25 is preferably an electrical erasable programmable read only memory (EEPROM) of the type well known in the art. As is known to those skilled in the art, memory 25 includes a programmable memory array, address decoders, and appropriate output buffers, all of which is well known to those skilled in the art. Memory 25 also includes clocking and sequencing circuitry for outputting the data stored therein. Memory 25 is programmed with identifying data for the pill. Typically, the identifying data is programmed into memory 25 by the manufacturer of the pill. This identifying information can include the identity of the drug or medication of the pill and the dosage level of the pill. The data may also include such information as lot number, date of manufacture, location of manufacture, or any other information the manufacturer may desire or be required to include in memory 25, such as a unique serial number so that each pill can be separately identified even from identical pills of the same lot. The size of memory 25 is large enough to contain the data.

Transponder 15 includes on-board data communication circuits, which is essentially the modulation site of a modem. The output from memory 25 is coupled to the input of a voltage controlled oscillator (VCO) 27. The VCO 27 produces a signal the frequency of which is related to the input voltage. The output for memory 25 is either a high voltage level or a low voltage level. Thus, VCO 27 applies frequency-shift keying (FSK) to the data received from memory 25. As is well known to those skilled in the art, higher transmission rates can be obtained using phase-shift keying (PSK), quadrature amplitude modulation (QAM), or other modem technologies. The FSK signal produced by VCO 27 modulates an RF signal produced by an RF oscillator 29. The modulation occurs in a mixing circuit 31. The modulated output from mixing circuit 31 is output to a radio frequency amplifier 33. Amplifier 33 amplifies the signal and

outputs the amplified signal to an antenna 35. Antenna 35 may be a separate antenna carried by transponder 15, or it may be power coil 21.

Antenna 35 of transponder 15 radiates the data modulated RF signal exterior of transponder 15. The data-modulated RF signal is received by a radio frequency receiver 37, which is part of monitoring station 17. Radio frequency receiver 37 is a conventional receiver and it preferably includes an on-board modem for demodulating the signal. Radio frequency receiver 37 is coupled to a CPU 39, which decodes the data received from transponder 15. Monitoring unit 17 includes a display 41 connected to CPU 39. Display 41 may be a simple LED display. Alternatively, display 41 may be a video monitor with elaborate graphical features.

Referring now to FIGURE 3, there is illustrated a coss section of a transponder, preferably comprising a spherical-shaped semiconductor device on which an integrated circuit has been formed. Such a spherical-shaped integrated circuit semiconductor device (sometimes referred to herein as a "ball") is described in, commonly assigned, U.S. Patent No. 5,955.776, filed May 16, 1997, issued September 21,1999, and entitled "Spherical Shaped Semiconductor Integrated Circuit," the disclosure of which is incorporated herein by reference. Transponder 15 is built on a substantially spherical semiconductor substrate 43, which may be doped P-type or N-type in accordance with the particular requirements of the fabrication process. Semiconductor circuitry indicated generally at 45 resides on substrate 43. Circuitry 45 includes the elements illustrated in FIGURE 2, including power regulator 23, memory 25, voltage controlled oscillator 27, RF oscillator 29, mixing circuit 31, and amplifier 33, as well as other circuitry. Substrate 43 and circuitry 45 are covered with an insulating layer 47. Insulating layer 47 is preferably formed of silicon dioxide or phosphosilicate glass. A power coil 21, described with respect to FIGURE 2, is formed of helically wrapped windings over the insulating shell 47. Power coil 21 may be fabricated from a deposited layer of aluminum that is patterned and etched using conventional semiconductor fabrication techniques. The actual number of individual windings of power coil 21 may be far greater than the six shown in FIGURE 3.

Transponder 15 is coated with or encapsulated in a coating layer 49 of a biological inert material such as phosphosilicate glass. Coating 49 can withstand the acidity of the stomach to a very low pH level and it is not subject to the enzymatic actions of the digestive tract. Additionally, coating 49 is inert to and does not react with the material of the pill 13.

Transponder 15 is substantially spherical and preferably about one millimeter in diameter. The very small size of transponder 15 enables it to be embedded in a pill 13 without increasing substantially the overall volume of the pill. However, the device should be made large enough not to be absorbed through the microvilli in the lining of the digestive tract.

Referring now to FIGURE 4, there is illustrated an alternative embodiment having a pair of interconnected spherical ball devices forming the transponder. The transponder 51 comprises two individual balls interconnected by metal contacts or solder bumps 53. The balls of transponder 51 include a circuit ball 55 and a memory ball 57. Balls 55 and 57 are constructed in the manner illustrated with respect to FIGURE 3. The sensor ball 55 includes a substantially spherical semiconductor substrate upon which resides the power coil 21, power regulator 23, voltage controlled oscillator 27, RF oscillator 29, mixing circuit 31, and amplifier 33 of FIGURE 2. Similarly, the memory ball 57 includes a substantially spherical semiconductor substrate upon which resides memory 25 of FIGURE 2. By clustering one or more of the memory balls 57 with the circuit ball 55, the size of memory available to transponder 51 may be increased greatly. Transponder 51 is encapsulated in a biologically inert material such as phosphosilicate glass.

Referring now to FIGURE 5, there is illustrated a cross section view of the interface contacts along the line 5-5 of FIGURE 4 of a circuit ball. In this embodiment, four contacts 53a, 53b, 53c and 53d are implemented between the memory ball 57 and the circuit ball 55. The contacts 53a and 53b may be power contacts, such as a positive 3.0 volts and ground, which can be passed from the circuit ball 55 to the memory ball 57 by conductors on its surface using two of a group of similar contacts (designated collectively by numeral 53 in FIGURE 4). The contacts 53c and 53d may be data and control contacts for communications between the circuit ball 55 and memory ball 57. Note that this embodiment is not limited to two interconnected balls, but may comprise any number of balls interconnected to provide the desired function.

Referring now to FIGURE 6, there is illustrated a detailed block diagram of an alternative embodiment of the transponder/monitoring system, according to the disclosed architecture. A monitoring unit 61 includes an antenna/coil 63 that transmits RF power to an antenna/coil 65 of a ball transponder 67. Power is transported either by RF radiation or by magnetic coupling between antenna coil 63 and antenna coil 65. Monitoring unit 61 generates RF power with an RF oscillator 69 coupled to an RF amplifier 71. The RF amplifier 71 is coupled to antenna/coil 63.

The RF power received at antenna/coil 65 of transponder 67 is rectified and smoothed by an RF rectifier smoother 73 coupled to antenna/coil 65. RF rectifier smoother 73 converts radio frequency energy to a DC voltage. DC power is stored in a DC power storage unit 75, which preferably includes a capacitor. The capacitor of DC power storage unit 75 may be included in the smoothing portion of the RF rectifier smoother 73. A voltage regulator 77 is coupled to DC power storage unit 75. Voltage regulator 77 makes the DC voltage powering transponder 67 stable for any condition or distance between monitoring unit 61 and transponder 67. Voltage regulator 77 supplies DC voltage to all circuits of transponder 67 in a manner well known to those skilled in the art. Transponder 67 includes a non-volatile memory 79, which is programmed with identifying information. The output from memory 79 is converted to a frequency signal by a converter 81. Control logic 83 controls converter 81. Control logic 83 may control the activity of all the circuits on transponder 67, though only a connection to converter 81 is shown in FIGURE 6. Control logic 83 may be a signal processor.

To transmit information, transponder 67 includes an RF oscillator 85. The frequency of RF oscillator 85 is preferably not the same as the frequency generated by RF oscillator 69 of control unit 61. The RF signal produced by RF oscillator 85 is modulated with the signal produced by converter 81 in an RF modulator 87. The modulated RF signal is amplified by an RF amplifier 89, which is coupled to antenna/coil 65. Transponder 67 may operate under AM, FM, PM, or other analog or digital modulation methods. The information transmitted from transponder 67 is received at antenna coil 63 of monitoring unit 61. The RF signal received at antenna/coil 63 is detected by an RF detector 91 and amplified by an RF amplifier 93. The amplified RF signal is converted to a digital signal by a converter 95, which is an A/D (analog-to-digital) converter or a demodulator. Converter 95 is coupled to control logic 97, which processes the data received from transponder 67, and controls a display 99 and other electrical circuitry of monitoring unit 61. Display 99 is either a display to a human operator or it may be an interface to other equipment.

Referring now to FIGURE 7, there is illustrated a more detailed schematic block diagram of the monitor and the transponder/monitoring system, according to a disclosed embodiment. The transponder 67, as described hereinabove, is operable to provide unique information according to its programmed instructions. The illustrated embodiment of FIGURE 7 is that associated with a "passive" system, which term refers to a system having no battery associated

therewith. In order to operate the system, there is provided an inductive coupling element 704 in the form of an inductor, which is operable to pick up an alternating wave or impulse via inductive coupling, and extract the energy therein for storage in the inductive element 704. This will create a voltage across the inductive element 704 between a node 706 and a node 708. A diode 710 is connected between the node 708 and the node 712, with the anode of diode 710 connected to node 708 and the cathode of diode 710 connected to a node 712. Typically, the diode 710 will be fabricated as a Schottky diode, but can be a simple PN semiconductor diode. For the purposes of this embodiment, the PN diode will be described, although it should be understood that a Schottky diode could easily be fabricated to replace this diode. The reason for utilizing a Schottky diode is that the Schottky diode has a lower voltage drop in the forward conducting direction.

The diode 710 is operable to rectify the voltage across the inductive element 704 onto the node 712, which has a capacitor 714 disposed between node 712 and node 706. Node 712 is also connected through a diode 716 having the anode thereof connected to node 712 and the cathode thereof connected to a node 718 to charge up a capacitor 720 disposed between node 718 and 706. The capacitor 720 is the power supply capacitor for providing power to the transponder 67. The capacitor 714, as will be described hereinbelow, is operable to be discharged during operation of the system and, therefore, a separate capacitor, the capacitor 720, is required for storing power to power the system of the transponder 67.

A CPU 738 is provided to control and process on-board functions of the transponder 67. A clock circuit 740 provides timing to the system. A memory 739 is provided in communication with the CPU 738 to allow the CPU 738 to store data therein for later transmittal back to the remote location or for even storing received instructions. This memory 739 can be volatile or it can be non-volatile, such as a ROM, and can be used to store unique information according to its programmed function. For the volatile configuration, of course, this will lose all information when the power is removed. The memory 739 is also connected to an A/D converter 736 for conversion of the memory data prior to transmission to the monitoring station 61, or the memory data may be pulled from the memory 739 by the CPU 738 for conversion to the A/D converter 736. System power to all power-consuming elements of the monitor 10 is provided at the SYSTEM PWR output node.

In order to communicate with the CPU 738 for transferring data thereto and for allowing the CPU 738 to transfer data therefrom, a receive/transmit circuit 742 is provided for interfacing to node 712 through a resistive element 744. This allows RF energy to be transmitted to node 712. It is important to note that the semiconductor junction across diode 710 is a capacitive junction. Therefore, this will allow coupling from node 712 to node 708. Although not illustrated, this could actually be a tuned circuit, by selecting the value of the capacitance inherent in the design of the diode 710. In any event, this allows an RF connection to be provided across diode 710 while allowing sufficient energy to be input across conductive element 704 to provide a voltage thereacross for rectification by the diode 710 and capacitor 714. Typically, the frequency of this connection will be in the MHz range, depending upon the design. However, many designs could be utilized. Some of these are illustrated in Beigel, U.S. Patent No. 4,333,072, entitled "Identification Device," issued June 1, 1982, and Mogi et al, U.S. Patent No. 3,944,982, entitled "Remote Control System For Electric Apparatus," issued March 16, 1976, both of which are incorporated herein by reference. With these types of systems, power can continually be provided to the node 712 and subsequently to capacitor 720 to allow power to be constantly applied to the transponder 67.

The remote monitor system 61 which is disposed outside of the body and proximate to the transponder 67 includes an inductive element 750 which is operable to be disposed in an area proximate to the skin, yet exterior to the body, in the proximity of the transponder 67. The inductive element 750 is driven by a driving circuit 752 which provides a differential output that is driven by an oscillator 754. This will be at a predetermined frequency and power level necessary to couple energy from inductive element 750 to inductive element 704. Since this is an external system, the power of the oscillator can be set to a level to account for any losses through the body tissues. To allow information to be transmitted, a modulation circuit 756 is provided which is modulated by a transmitter signal in a block 758 that allows information to be modulated onto the oscillator signal of the oscillator 754, which oscillator signal is essentially a "carrier" signal. However, it should be understood that the information that is transmitted to the transponder 67 could merely be date information, whereas the CPU 738 could operate independent of any transmitted information to provide the correct timing for the output pulses and the correct waveshape therefor. Alternatively, entire control of the system could be provided by the transmit signal 758 and the information carried thereon, since power must be delivered to the illustrated embodiment due to the lack of any independent power in the transponder 67.

When the information is received from the transponder 67, it is superimposed upon the oscillator signal driving the inductive element 750. This is extracted therefrom via a detector 760 which has the output thereof input to a first low pass filter 762, and then to a second low pass filter 764. The output of low pass filters 762 and 764 are compared using a comparator 766 to provide the data. The filter 762 provides an average voltage output, whereas the filter 764 provides the actual digital voltage output. The output of the comparator 766 is then input to a CPU 770 which also is powered by the oscillator 754 to process the data received therefrom. This can then be input to a display 772.

Referring now to FIGUREs 8A-8C, there are illustrated alternate embodiments for the transmit/receive operation. In FIGURE 8A, there is provided an oscillator 800 which drives an external inductive element 802. Typically, there is some type of load 804 disposed across the inductive element 802. This is the primary power that is provided to the system. A separate inductive element 806 is provided on the transponder 67, for being inductively coupled to the inductive element 802. Thereafter, a voltage is generated across the inductive element 806, the inductive element 806 being connected between nodes 808 and 810. A diode 812 is connected between node 808 and a power node 814, and a power supply capacitor 816 is disposed across node 814 and a node 810. This allows the voltage on node 808 to be rectified with diode 812.

In FIGURE 8B, the receive operation, in this alternative embodiment, utilizes a separate inductive element or antenna 824 in the transponder 67, which is operable to be connected between nodes 809 and 811. Node 809 is capacitively coupled to a transmit node 830 with a capacitor 832, the capacitor 832 being a coupling capacitor. A transmitter 834 is provided for transmitting received data from a line 836 to the node 830, which is then coupled to the node 809 to impress the RF signal across the inductive element 824.

A corresponding inductive element 840 is disposed on the external remote controller of remote monitoring location 61, which inductive element 840 is operable to be disposed proximate to the inductive element 824, but external to the human body. The inductive element 840 is basically a "pick-up" element which is operable to receive information and function as an antenna, and provide the received signal to a receiver 842. The structure of FIGURE 8B is a separate structure, such that node 809 is isolated from node 808, the power receiving node. However, it should be understood that any harmonics of the oscillator 800 would, of course, leak

over into the inductive element 824. This can be tuned out with the use of some type of tuning element 844 on the transponder 67 disposed across inductive element 824, and also a tuning element 846 disposed across the inductive element 840, i.e., the antenna.

Referring now to FIGURE 8C, there is illustrated a simplified schematic diagram of the receive portion. The transponder 67 has associated therewith a separate receive antenna or inductive element 850 disposed between node 813 and a node 852. Node 852 is capacitively coupled to a receive node 854 with a coupling capacitor 856. A receiver 858 is provided for receiving the information transmitted thereto and providing on the output thereof data on a data line 860. The receiver 858 is operable to receive the RF signal, demodulate the data therefrom, and provide digital data on the output 860. External to the human body and the transponder 67 is a transmitter 862 which is operable to impress a signal across an external inductive element 864. The inductive element 864 basically provides the RF energy and is essentially tuned with a tuning element 866. A corresponding tuning element 868 is provided on the transponder 67 and disposed across inductive element 850, the inductive element 850 acting as an antenna, as well as the inductive element 864.

Note that in circumstances where the signals of transponder 67 cannot be adequately received therefrom and/or power coupled thereto, the external location circuitry 61 may need to be inserted into the body proximate to the transponder 67 in order to couple the transmit/receive signals and power. Furthermore, where more than one transponder ball 67 is used, communication of power and data signals between the various transponders 67 may need to employ distinct time periods (i.e., time multiplexing) when communication occurs using a single common frequency, or discrimination circuits may need to be used where communication occurs simultaneously with the plurality of implanted transponders 67 having different oscillator frequencies.

Referring now to FIGURE 9, there is illustrated a side view of an alternative embodiment utilizing additional circuitry or structure attached to a transponder for providing a local power source. As described hereinabove, the transponder 67 requires a power-generating structure for storing a power supply voltage such that diodes must be provided for receiving and rectifying a large amount of power and charging up a power supply capacitor. Alternatively, the transponder 67 could be configured to interface to an attached power supply system 900 comprising either a

battery or a capacitor. The local power supply system 900 is illustrated as disposed on a circuit board 903 defined by supporting structures 902 and 904. The circuit board 903 contains electronics for interfacing the local power supply system 900 to the transponder 67.

Referring now to FIGURE 10, there is illustrated a schematic block diagram of the transponder 67 having a battery as the local power supply system 900. A battery 1001 is provided as a source of self-contained power and is connected across a capacitor 1000 to providing smoothing of any power output to the system power-consuming elements of the transponder 67. Power for all on-board components is obtained from the SYSTEM POWER output by providing sufficient charge to the capacitor 1000. The capacitor 1000 could be formed on the surface of the transponder 67 or it could actually be part of the battery structure 1001. Additionally, the capacitance 1000 could actually be the capacitance of the battery 1001. Additional structure could be provided for powering the CPU 738 and the other circuitry on the transponder 67 from the battery 1001. As such, there would only be required a smaller inductive element 1002 and a capacitor 1004 to allow the receive/transmit block 742 to receive/transmit information from and to the remote exterior station 61. The memory 739 and A/D 736 connect to the CPU 738, and optionally, to one another to facilitate conversion of the stored memory data prior to transmission from the transponder 67 to the monitor station 61.

Referring now to FIGURE 11, there is illustrated a perspective view of the transponder 67, wherein the inductive element 704 (inductive element 1002 being similar thereto) is illustrated as being strips of conductive material wrapped around the outer region of the transponder 67. The inductive element 704 is formed of a conductive strip wrapped many times around the transponder 67. The length of inductive element 704 depends upon the receive characteristics that are required. As described hereinabove with reference to FIGUREs 8A-8C, there could be multiple conductive strips, each associated with a receive function, a transmit function or a power function, or they could all share one single conductive element or strip. On either end of the transponder 67 there are provided interface balls (or partial balls called nodules) 1102 which can be made of non-reactive material, e.g., gold, to prevent degradation while in use in the body. The interface nodules 1102 function as interface contacts with other balls, which other balls may be used to facilitate monitoring of quantitative data, or unique functions such as supplying only power or data buffering and storage.

Referring now to FIGURE 12, there is illustrated a cross-sectional diagram of the semiconductor surface of the transponder 67 illustrating the conductive strips forming the inductive element 704. The conductive strips are referred to by reference numeral 1210 which are spaced above the surface of the integrated circuit of the transponder 67 by a predetermined distance, and separated therefrom by a layer of silicon dioxide. A passivation layer 1211 is then disposed over the upper surface of the conductive strips 1210. The conductive strips 1210 can be fabricated from polycrystalline silicon but, it would be preferable to form them from the upper metal layer to result in a higher conductivity strip. This will allow the strips 1210 to be narrower and separated from each other by a larger distance. This separation would reduce the amount of capacitance therebetween.

One end of the strips 1210 is connected to a diode structure 1213 (e.g., diode 710 of FIGURE 7). The diode structure 1213 is formed of an N-well implant region 197 into which a P-well implant region 1216 is disposed, and an N-well implant region 1218 disposed within the P-well implant region 1216. This forms a PN diode where one end of the conductive strips 1210, a conductive connection 1220, is connected to the P-well 1216 implant region, and a conductive layer 1222 is connected at one end to the N-well implant region 1218. This conductive layer or strip 1222 extends outward to other circuitry on the integrated circuit and can actually form the capacitor. Since it needs to go to a capacitor directly, a lower plate 1224 formed of a layer of polycrystalline silicon or metal in a double-metal process, could be provided separated therefrom by a layer of oxide.

From the foregoing, it may be seen that the device of the disclosed embodiment provides an almost microscopic spherical integrated circuit transponder or ball that can be imbedded in pills (medication in pill, capsule, or any other ingested form), and other medical items, to provide a method of positive identification. The ball contains specific information in each pill such as the type of medication, its authenticity, dosage, manufacturer, lot number, date of manufacture, and date of expiration. Because of its size and its biologically inert properties, the ball is undigested and unaffected by the acid environment of the stomach. A small antenna on the ball allows it to send and receive radio frequency signals (RF transponder). The ball is eliminated from the body with normal bowel movements. The cost of the disclosed ball transducer 67 is sufficiently low and affordable to allow its inclusion in the smallest unit of medication. Simple RF sensing devices will be used to interrogate the transponder 67 within the pill and identify it beyond a

level currently available with any existing system. It can be appreciated that pills for animals can be coded similarly to provide the same benefits. It would also provide a robust method of identifying which medications are for human or for veterinary use.

The positive, discrete identification of commercially manufactured medications at the single dosage level will improve many pharmaceutical activities including inventory control, distribution, prescription filling and the actual dispensing of medications to the patient. It will also have a major impact on medical practice by permitting health care workers to identify positively which medications the patient has taken and how many pills remain within the patient's body. This information can be obtained from patients who are not able to provide a medication history on their own (e.g. forgetful, memory-impaired, or unconscious patients). The radio-frequency signal from each pill would also provide some general information about its location within the gastrointestinal tract, from the esophagus through the colon.

In addition to pills, the transponder 67 may be used to tag any medical product or device. For example, the transponder may be affixed or otherwise attached to a surgical sponge. The transponder 67 would contain data to identify the sponge. Before closing, the patient's body at the site of the surgery would be scanned with a monitoring unit. If a sponge ball transponder 67 were to respond, the sponge could be located and removed. Other medical items, such as surgical instruments, may be similarly tagged with the ball transponder 67. The instruments could be scanned before surgery to generate an inventory. At the conclusion of surgery, the surgical suite can be scanned to account positively for all items in the inventory.

If every medical item and supply in the hospital or doctor's office is tagged, the trash cans or trash bags can be scanned. The scanning can also be done for billing purposes. Hospitals now use bar codes for billing supply items. The ball tags would be incorporated into the medical items, so the items are intact and can be scanned even after the package has been opened and discarded. Because the ball ID tags are small and inexpensive, they can be inserted into or attached to virtually every medical item or any other product.

Although the preferred embodiment has been described in detail, it should be understood that various changes, substitutions and alterations can be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A method of identifying a medical product, which comprises the steps of:

tagging the medical product with an externally powered transponder, the transponder have memory associated therewith; and

storing in the memory identifying data for the product.

2. The method of Claim 1, including the step of reading the memory externally of the product to obtain the identifying data.

3. The method of Claim 2, wherein the step of reading the memory externally of the product includes the steps of:

generating electromagnetic radiation externally of the product to power the transponder;

modulating an RF signal with the identifying data in the transponder and transmitting the RF signal;

receiving the modulated RF signal externally of the product; and

extracting the data from the modulated RF signal.

4. The method of Claim 1, wherein the transponder is formed on a single semiconductor substrate.

5. The method of Claim 4, wherein the semiconductor substrate is substantially spherical.

6. The method of Claim 5, wherein the transponder is about one millimeter in diameter.

7. The method of Claim 1, wherein the medical product is a pill.

8. The method of Claim 7, wherein the tagging step includes the step of imbedding the transponder in the pill.

9. A system for identifying a medical product, comprising:

a medical product having application with an organic body; and

an externally powered transponder having a memory containing identifying data, said transponder attached to said medical product for identifying the medical product.

10. The system of Claim 9, wherein said memory is read by a monitor system proximate to the medical product to obtain said identifying data.

11. The system of Claim 9, wherein the memory is read when an external power generation circuit powers said transponder causing said identifying data to modulated on an RF signal and transmitted to a monitor system proximate to said transponder.

12. The system of Claim 9, wherein said transponder is formed on a single semiconductor substrate.

13. The system of Claim 12, wherein said semiconductor substrate is substantially spherical.

14. The system of Claim 13, wherein said transponder is about one millimeter in diameter.

15. The system of Claim 9, wherein the medical product is a pill.

16. The system of Claim 15, wherein the transponder is embedded in said pill.

17. The system of Claim 9, wherein the medical product is a surgical tool used during surgery of said organic body which is a human patient.

18. A method of identifying a pill, which comprises the step of:

imbedding an externally powered transponder in the pill, the transponder having memory associated therewith; and

storing in the memory identifying data for the pill.

19. The method of Claim 18, including the step of reading the memory externally of the pill to obtain the identifying data.

20. The method of Claim 19, wherein the step of reading the memory externally of the pill includes the steps of:

generating electromagnetic radiation externally of the pill to power the transponder;

modulating an RF signal with the identifying data in the transponder and transmitting the RF signal;

receiving the modulated RF signal externally of the product; and

extracting the data from the modulated RF signal.

21. The method of Claim 18, wherein the transponder is formed on a single semiconductor substrate.

22. The method of Claim 21, wherein the semiconductor substrate is substantially spherical.

23. The method of Claim 22, wherein the transponder is approximately one millimeter or less in diameter.

24. The method of Claim 22, wherein the transponder is substantially large to prevent absorption through microvilli of a digestive tract.

25. The method of Claim 18, wherein the transponder is encapsulated with a substantially biologically inert coating.

26. The method of Claim 18, wherein the identifying data includes the identity of the medication of the pill.

27. The method of Claim 18, wherein the identifying data includes the dosage of the medication of the pill.

28. The method of Claim 18, wherein the identifying data includes the identity of the manufacturer of the pill.

29. The method of Claim 18, wherein the identifying data includes the date of manufacture of the pill.

30. An oral medication, comprising:

a pill; and

an externally powered transponder imbedded in said pill, said transponder including a memory containing identifying data of said pill.

31. The oral medication of Claim 30, wherein said transponder comprises:

a semiconductor substrate;

means residing on said substrate for modulating an RF signal with data contained in said memory; and

means residing on said substrate for powering circuitry residing on said substrate in response to an external electromagnetic signal.

32. The oral medication of Claim 31, including a biologically inert coating covering said transponder.

33. The oral medication of Claim 32, wherein said coating comprises glass.

34. The oral medication of Claim 31, wherein said means for powering said circuitry includes a power coil residing on said substrate.

35. The oral medication of Claim 31, wherein said substrate is substantially spherical.

36. The oral medication of Claim 30, wherein said transponder comprises:

a circuit ball electrically coupled to said memory, said circuit ball comprising a substantially spherical substrate and circuitry residing on said substrate for modulating an RF signal with data contained in said memory; and

means for powering said RF modulating circuitry.

37. The oral medication of Claim 36, wherein said memory resides on said spherical substrate of said circuit ball.

38. The oral medication of Claim 36, wherein said memory resides on a substantially spherical memory ball electrically coupled to said circuit ball.

39. The oral medication of Claim 36, wherein said means for powering said RF modulating circuitry includes power circuitry residing on said circuit ball for generating power in response to an external electromagnetic signal.

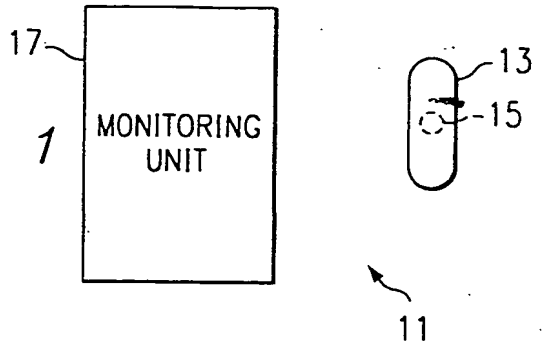


FIG. 1

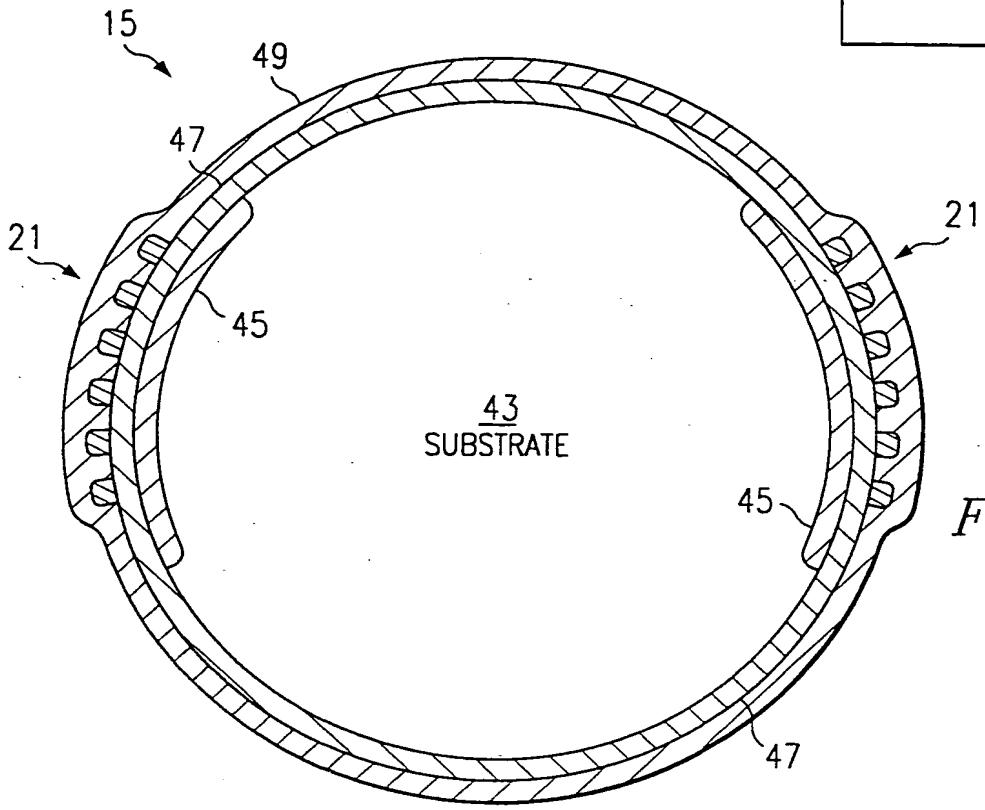


FIG. 3

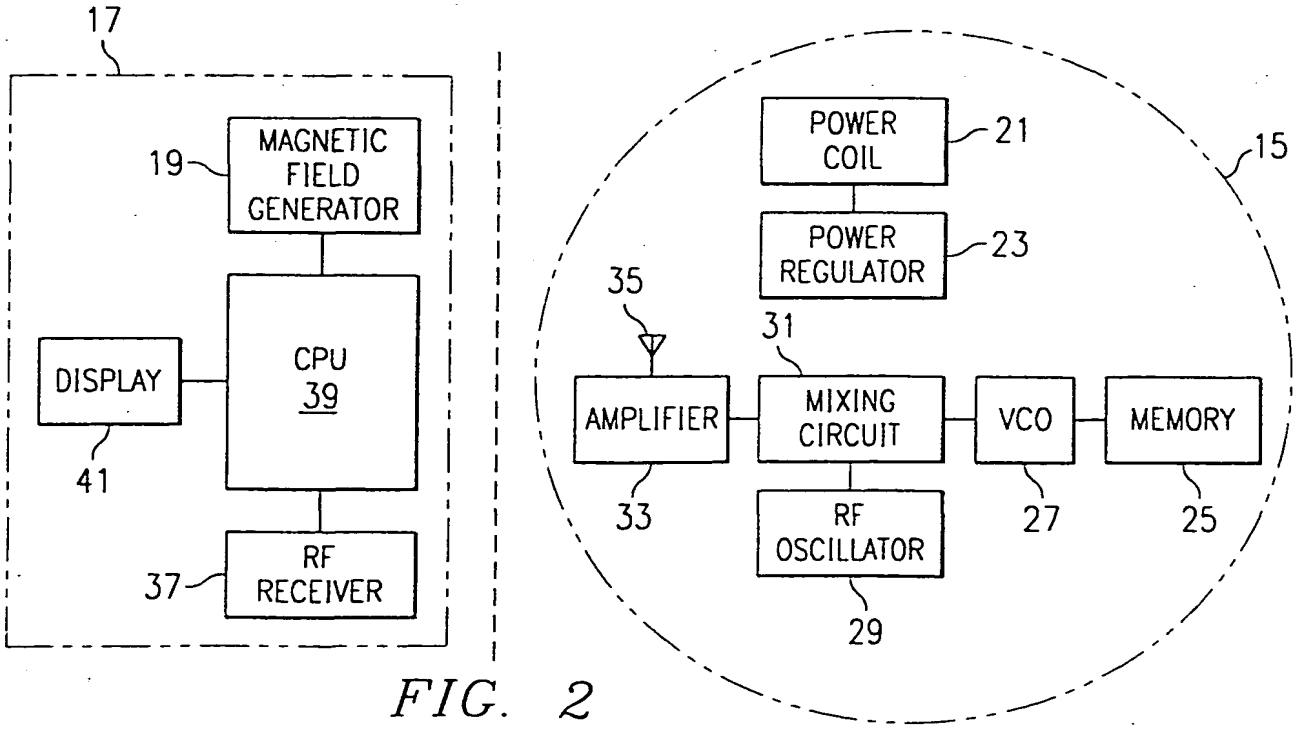


FIG. 2

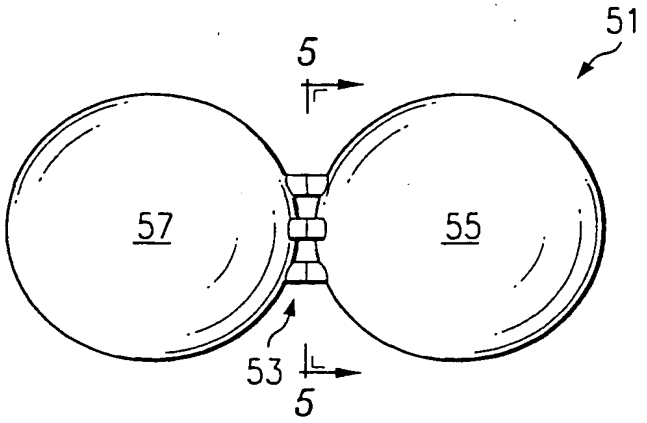


FIG. 4

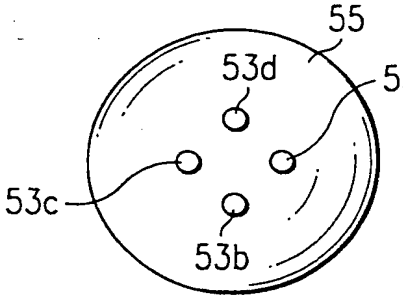


FIG. 5

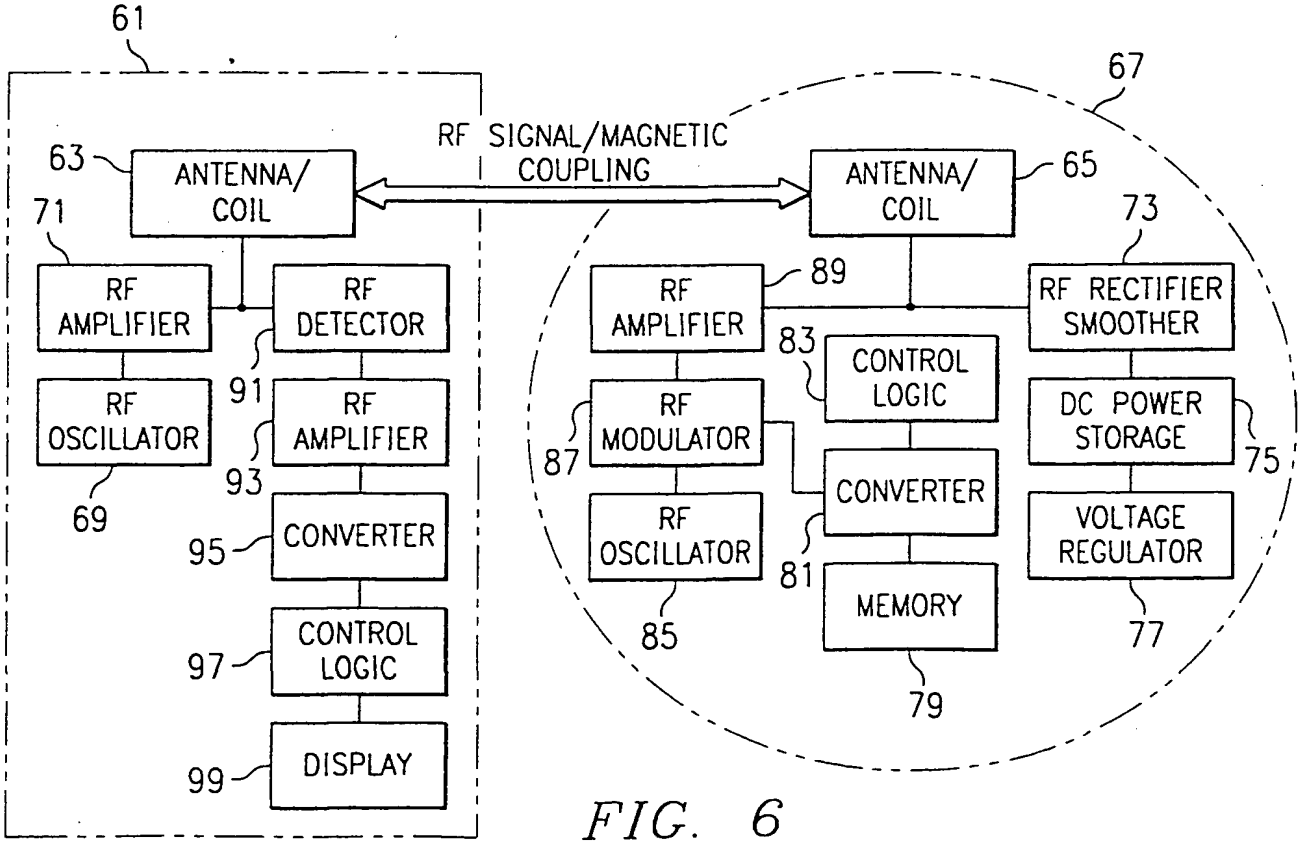


FIG. 6

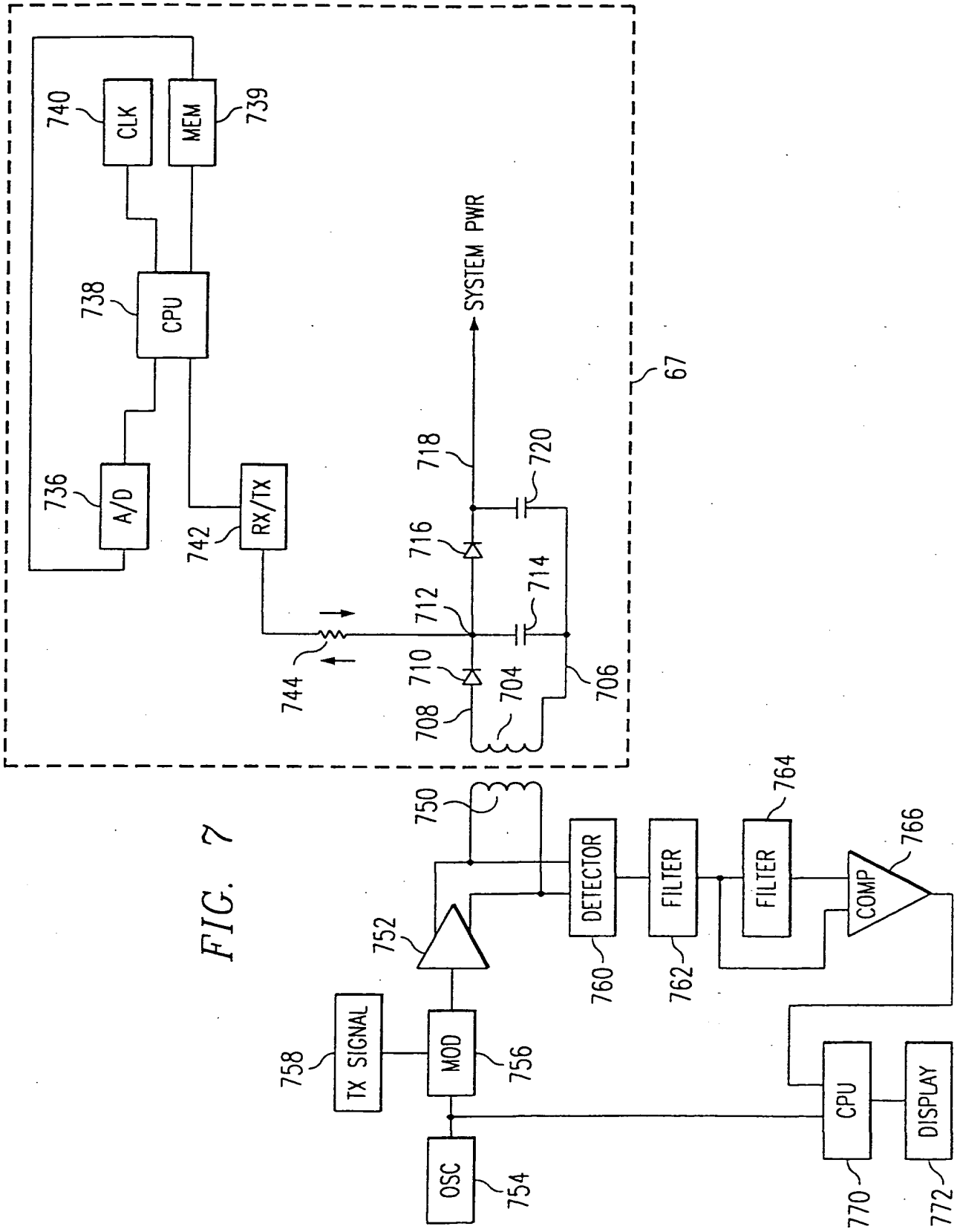


FIG. 7

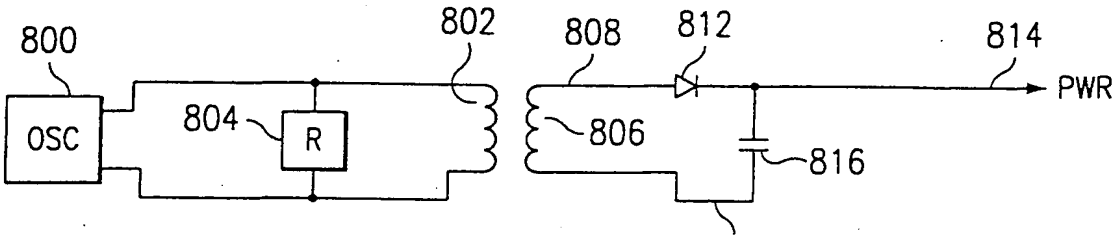


FIG. 8A

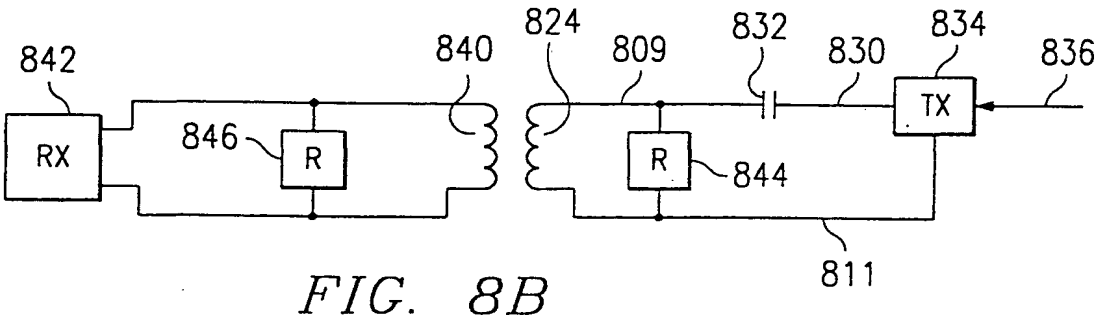


FIG. 8B

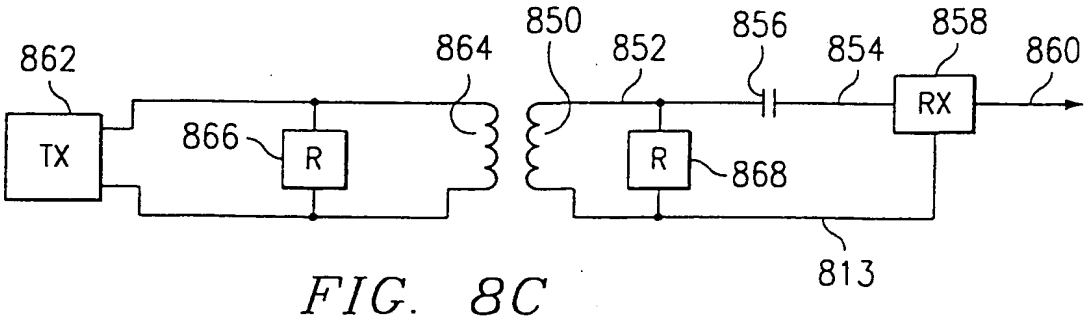


FIG. 8C

FIG. 9

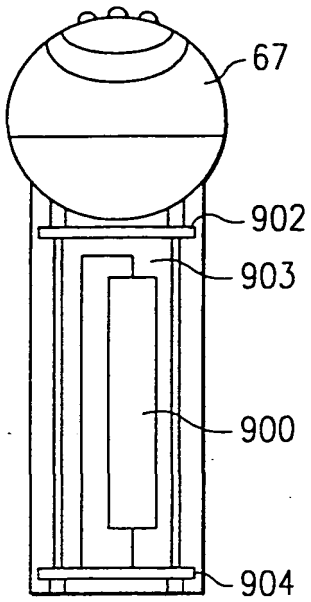


FIG. 10

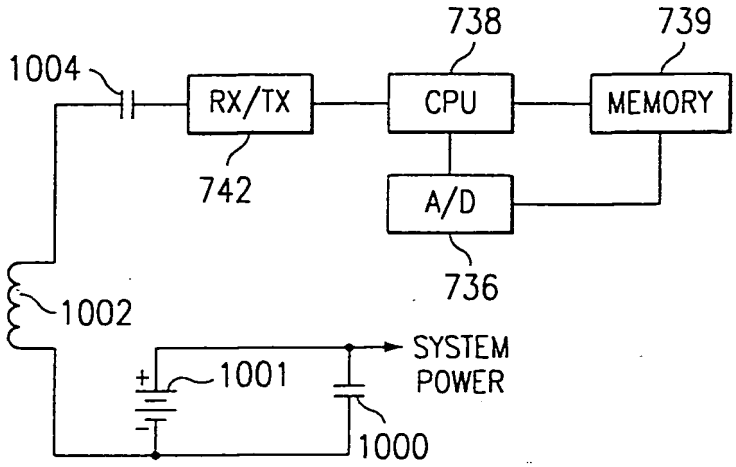


FIG. 11

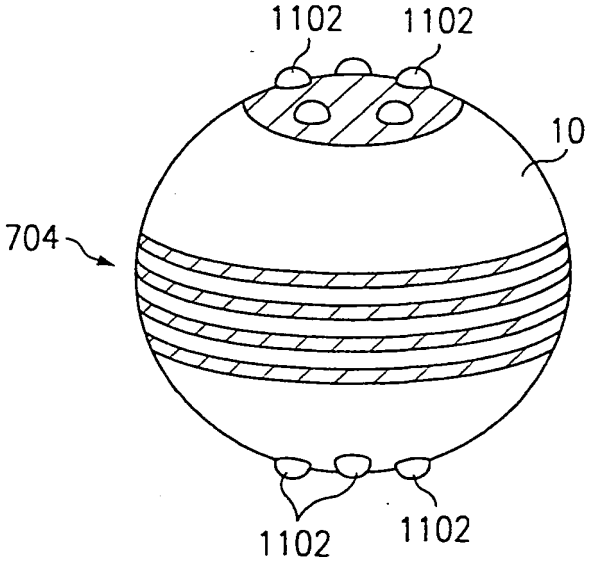
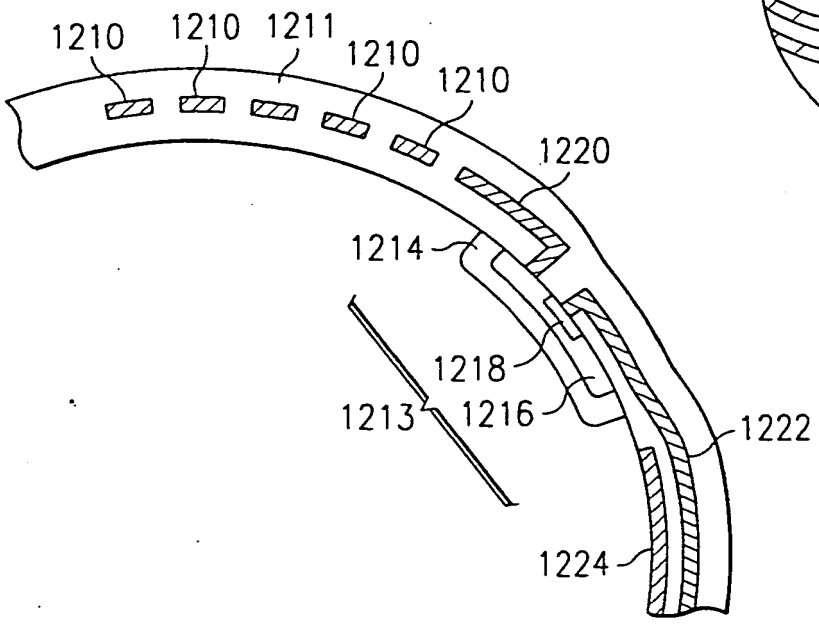


FIG. 12



INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/28095

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G06K19/07

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G06K G01V A61F G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 725 578 A (BELSEY ELIZABETH MARY ET AL) 10 March 1998 (1998-03-10)	1-3, 7-11,15, 16, 18-20, 25-29
Y		4-6, 12-14, 21-24
A	abstract column 1, line 45 -column 2, line 67 column 5, line 42 -column 6, line 67 figures 1,20	30-37,39

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 March 2000	30/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Jacobs, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/28095

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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